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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,355	06/23/2003	Minggiang Zhang	O 1999.507 US D1	2578
31846	7590	02/08/2005	EXAMINER	
AKZO NOBEL PHARMA PATENT DEPARTMENT			MAIER, LEIGH C	
PO BOX 318			ART UNIT	
MILLSBORO, DE 19966			PAPER NUMBER	
			1623	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/603,355

**Applicant(s)**

ZHANG ET AL.

**Examiner**

Leigh C. Maier

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Priority***

The instant application has been filed as a divisional of USSN 10/148,307, now US 6,670,340. It is noted that no restriction requirement was made in the parent case. That is, the instant invention has never been deemed to be patentably distinct from the invention that is claimed in the parent.

### ***Claim Objections***

Claim 14 is objected to because of the following informalities: "Cyclodextrin" is misspelled (line 3). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from claims that have been canceled, thereby rendering them vague and indefinite.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,670,340. Although the conflicting claims are not identical, they are not patentably distinct from each.

The instant claims are drawn to a kit comprising a neuromuscular blocking agent (NMBA) and a cyclodextrin (CD) derivative. The CD derivative is selected from a group of six particular species. Reference claim 7 is drawn to a kit comprising an NMBA, with species recited, and a CD derivative. The reference claim differs from the instant claims because it is broader in scope and does not recite the species required in the instant claim. However, it would have been obvious to select the species because these particular species are disclosed. See reference claim 4 and col 4, lines 56-67.

Claims 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,670,340 in view of POLI et al (US 5,767,112).

Claims 15 and 16 are drawn to a method of treating a patient with an NMBA comprising administration of an NMBA followed by reversal of the neuromuscular block by administration

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of a CD derivative. The CD derivative is selected from a group of six particular species noted above. Reference claim 9 is drawn to a method for reversal of drug-induced neuromuscular block in a patient by administering a CD derivative.

The reference claim differs from the instant claims because it is broader in scope and does not recite the species required in the instant claim. Neither does the claim require the step of administering the blocking agent.

POLI teaches that NMBAs, such as rocuronium, are used in surgical anesthesia for relaxation of skeletal muscles. See col 1, lines 17-23 and col 2, lines 35-41.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of claim of claim 9. The fact that the claim recites “reversal of drug-induced neuromuscular block in a patient” clearly suggests the step of inducing the block. It would have been obvious to select any common NMBA, such as rocuronium, to induce a block for surgery with a reasonable expectation of success. Furthermore, the disclosure suggests kits for this purpose. See reference claim 6. It would have been further obvious to select the species because these particular species are disclosed, as discussed above.

#### ***Allowable Subject Matter***

The claims appear to be free of the art. UDA et al (US 5,840,881) teaches the use of carboxylate-derivatized CDs as solubilizers for a wide variety of compounds, including muscle relaxants, such as tubocurarine or pancuronium. See abstract and col 9, lines 6-7. The reference does not teach the instant CD derivatives, nor does it teach or fairly suggest the use of the disclosed CDs for the reversal of a neuromuscular block.

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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

*Leigh C. Maier*

Leigh C. Maier  
Patent Examiner  
February 7, 2005